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09/016,159	01/30/1998	JONG Y. LEE	07004-002004	6621

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/016,159

Applicant(s)

LEE, JONG Y.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3,5 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1a. Receipt of Applicant's amendment and arguments, filed on 22 June 2004 is acknowledged. Claims 3, 13 and 14 have been amended. New claims 15-16 have been added.

#### ***Status of Claims:***

1b. Claims 3, 5 and 10-16 are pending. Claim 10 stands withdrawn from consideration as it is drawn to non-elected invention. Claims 3, 5 and 11-16 are under consideration.

#### ***Sequence Submission:***

2. Applicant submitted new sequence listing which contains three sequences. The instant application originally contained 5 sequences, SEQ ID Nos: 1-5, of which SEQ ID NO:5 represents polypeptide sequence that consists of 508 amino acid residues. The newly submitted sequence listing contains 3 sequences, SEQ ID NO:1, which is an amino acid sequence that consists of 508 amino acid residues, SEQ ID NO:2, which is a nucleotide sequence that consists of 1527 bases and SEQ ID NO:3 which is a polypeptide sequence that consists of 508 amino acid residues. Applicant's amendment to the specification cites SEQ ID Nos: 5, 6 and 7, however, it is unclear whether these SEQ ID Nos, are referring to the originally filed sequence listing or to the newly filed sequence listing. Clarification of the numbering of the SEQ ID Nos is required.

#### ***Response to Applicant's Argument:***

3. The following previous rejection are withdrawn in light of Applicants amendments filed on 06/22/04:

(I) The rejection of claims 3 and 13 made under 35 U.S.C. 101, for not reciting "isolated", is withdrawn, because the amended claims now recite "isolated".

(II). The rejection of claims 3, 5, and 11-14 made under 35 U.S.C § 102(b) as being anticipated by Jones et al (published July 1990), is withdrawn, because Applicant's argument that the polypeptide disclosed by Jones et al is expressed from full-length Epo receptor DNA is found persuasive. Also Applicant's argument that the polypeptide of Jones et al has a molecular weight of 66 kDa, rather than the 29 kDa recited in claim 3 is persuasive.

***Maintenance of Previous Rejections:***

***Claim Rejections - 35 U.S.C. § 112:***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 3, 5, 11, 12-14 made under 35 U.S.C. 112, first paragraph is maintained for reasons of record set forth in the office action mailed on 14 May 2004, pages 2-5.

Applicant argues that it is not correct under the law that the description of one polypeptide is not adequate written description for a genus and that the Applicants has described the structure of two members of the genus, namely SEQ ID NO:5 and SEQ IDNO:7. Applicant further argues that she is not required to provide the exact chemical

structure of all species of a claimed genus of polypeptides. Applicant also argues that the instant specification meets the written description requirement, since it provides the structure of two members of the genus, discloses the function of the receptor polypeptide which is linked to the structure and since the skill level of the art is high, and can envision the claimed subject matter. Applicant submits that any functional isoform of human erythropoietin receptor polypeptide that differs from SEQ ID NO:5 or 7, would be immediately recognized, and thus the boundaries are clear. Applicant concludes that the description of two polypeptides (SEQ ID NO:5 and 7) is clearly adequate written description for the claimed invention.

These arguments have been considered, but are not deemed persuasive. It is correct that the description of one polypeptide is adequate written description for a genus, however, in the instant case the claims do not recite any specific SEQ ID NO. Applicant describes SEQ ID NO:5 as being encoded by the cDNA disclosed by Winlemann et al, and that SEQ ID NO:7 is encoded by the cDNA disclosed by Jones et al, and that the two polypeptides differ in 4 amino acid residues, (see the amendment to the specification filed on 22 June 2004). Thus, Applicant is correct in that the recitation of these sequences in the claims would provide adequate written description for the claimed invention, however, these sequences are not recited in the claims. As a result, the claims encompass polypeptides, which are not described by the Applicants, Applicant is arguing limitations that are not recited in the claims. As was indicated in the office action mailed on 14 May 2004, reciting the SEQ ID NOs: in claim 3 would obviate the rejection of claim 3 under 112, first paragraph.

With respect to the recitation “consisting essentially of”, reciting SEQ ID Nos: 5 and 7 in the claims is not sufficient to provide written description for claims that recite “consisting essentially of”. Applicants have not described all of the possible polypeptides that consist essentially of amino acids 25-250 of SEQ ID Nos: 5 or 7 and other amino acid residues, since Applicant has not described what other amino acid residues should the claimed polypeptides essentially consist of.

With respect to claims 11 and 13, Applicant only provides the description of the 5' end primer and the 3' end primer, however, Applicant does not describe the structure of the rest of the cDNA. Thus, these claims encompass polypeptides expressed from cDNAs that have not been described in the specification. The specification does not set forth that “all” polypeptides that are expressed from the 5' comprising SEQ ID NO:1 and the 3' comprising SEQ ID NO:2, would have a specific affinity for human erythropoietin. Thus, the instant specification has not set forth structural/functional correlation that may be definitive of a genus. Although the level of the skilled artisan is high, in the instant case the skilled artisan cannot envision each and every polypeptide expressed from the above mentioned primers that have specific affinity for human EPO.

5a. The rejection of claims 3, 5, 11, 12-14 made under 35 U.S.C. 112, second paragraph, is maintained for reasons of record set forth in the office action mailed on 15 May 2004.

Applicant's argument that the phrase “consisting essentially”, does not render the claims indefinite, but renders the claims open for the inclusion of only unspecified ingredients that do not materially affect the basic and novel characteristics of the

claimed composition, is not found persuasive. The phrase "consisting essentially" is used for a composition of matter, which consists of two or more components. However, the instant invention is drawn to a polypeptide, and there is no disclosure of what other amino acid residues that the claimed invention should "consist essentially of". Thus the metes and bounds of the claim cannot be ascertained, since it is unclear what else the claimed invention should consist essentially of.

***Conclusion:***

6. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
31 August 2004

*Brenda Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**